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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/826,165

04/16/2004

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889_001

8549

25191 7590 07/16/2008
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EXAMINER

YOUNG, MICAH PAUL

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

07/16/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/826,165	Applicant(s) KANIE, JIRO	
	Examiner MICAH-PAUL YOUNG	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 April 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Acknowledgment of Papers Received: Amendment/Response dated 4/15/08

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13 recites the limitation "product administration device" in line 1 of the claims. There is insufficient antecedent basis for this limitation in the claim. The claim is a product claims that is dependent on a method claim, however no where in the method claims is there an administration device mentioned.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 8, 10, 11 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Resmer (USPN 5,232,733 hereafter '733). The claims are drawn to a semi-solid enteral nutrient product comprising a nutrient liquid and a semi-solidifying agent such as agar.

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The '733 patent teaches a semi-solid enteral formulation comprising a nutrient liquid and an emulsifying agent (abstract). The nutrient liquid includes milk products such as skimmed and milk and milk proteins along with semi-solidifying agents such as agar-agar (col. 2, lin. 38-45, examples 1-4). The product is semi solid with a viscosity of 70 cp and is used in feeding tube devices where this is delivered to the patient under pressure from an exterior device (col. 4, lin. 49-60). The product is formed by mixing the nutrient liquid with the agar-agar components along with other nutritional components at an elevated temperature. The mixture is stored is homogenized, cooled and stored (col. 3, lin. 65-col. 4, lin. 48).

Regarding the claim limitation drawn to the specific application site or operating procedures of the feeding tube and where the tube is placed are merely limitations reciting a future intended use for the enteral product. The enteral product of the '733 patent is structurally identical tot hat of the instant claims. It comprises a nutrient liquid and a semi-solidifying component such as agar. Applicant is reminded that where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention, the preamble is not a claim limitation. See also *Rowe v. Dror*, 112 F.3d 473, 478, 42 USPQ2d 1550, 1553 (Fed. Cir. 1997).

Regarding claim limitations regarding the solidity of the product in the body, it is the position of the Examiner that such limitations would be inherently met by the '733 patent. The patent meets each of the compositional limitations of the claims namely it discloses an enteral feeding tube composition comprising a nutrient liquid and a semi-solidifying agents. By meeting these limitations any composition would inherently meet the functional limitation since those limitations would fall naturally from the properties of the components. Since a component and

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its properties cannot be separated the combination of the nutrient liquid and the agar must also remain in a semi-solid state in the intestine and not be affected by body temperature.

For these reasons the claims are anticipated by the '733 patent.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
1. Claims 8-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Resmer et al (USPN 5,232,733 hereafter '733) in view of in view of Kabushiki et al (***Total Parenteral Nutritional and Enteral Nutrition***, pg 283-307, Suppl. 5, *Nippon Rinsho*, vol. 59, no. 782). The claims are drawn to a formulation for enteral administration comprising a nutritional liquid and a solidifying agent; wherein the mixture is fed through a feeding tube of predetermined internal diameter.

As discussed above the '733 patent discloses a formulation useful in enteral feeding tube devices comprising a nutrient liquid and agar as a semi-solidifying agent. The patent is however silent to the diameter of the feeding tube, though feeding tube diameters are commonly known in the art as seen in the Kabushiki reference.

The Kabushiki reference discloses an enteral feeding method. The device administers thick fluid diets such as puddings or crèmes, using feeding tubes with internal diameters larger than 4 mm (diagram). It would have been obvious to use the pudding recipe of Ying in the feeding tube method described by Kabushiki since it would provide a diet high in calcium and low in sodium to a patient in need. Also the tubing of the Kabushiki patent would provide an even flow to the thick composition avoiding air-bubbles that would adversely affect the patient.

Regarding the specific concentration of agar in the mixture it can be seen that the agar is added in an amount approximately 1.5 g/l to 343 g of diluting water. The claims recite a 1 gram of agar per 200 ml of diluting water, measuring approximately 5 g/l of total formulation. By this ratio the prior art comprises approximately 4.37 g/l of total formulation. These concentrations would be the result of optimization for those of ordinary skill in the art. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *See In re Aller*, 220 F.2d 454 105 USPQ 233, 235 (CCPA 1955).

Furthermore the claims differ from the reference by reciting various concentrations of the active ingredient(s). However, the preparation of various compositions having various amounts of the active is within the level of skill of one having ordinary skill in the art at the time of the invention. It has also been held that the mere selection of proportions and ranges is not

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patentable absent a showing of criticality. *See In re Russell*, 439 F.2d 1228 169 USPQ 426 (CCPA 1971).

With these things in mind it would have been obvious to combine the feeding tube formulation of the '733 patent into the enteral administration device of the Kabushiki reference in order to provide an enteral formulation high in calcium to a patient in need thereof. It would have been obvious to use a feeding tube of sufficient diameter in order to ensure even flow and distribution. One of ordinary skill in the art would have been motivated to combine these disclosures with an expected result of an enteral feeding composition with a smooth even rate of flow directly to the intestine.

Response to Amendment

The Declaration filed under 37 CFR 1.132 filed 4/15/08 is insufficient to overcome the rejection of claims 8-13 based upon USC 102(b) and USC 103(a) as set forth in the last Office action because: The claims are not commensurate in scope with the specific invention discussed in the Declaration. The Declaration presents evidence of a long felt need for a half-solid enteral feeding tube composition. However the composition described in Appendix D is of a specific formulation comprising exact concentrations of agar and a nutrient liquid. However, applicant has not shown any comparisons between the closest prior art and the invention of the instant claims to show any specific unexpected result of reason why any semi solid pudding like agar formulation would not also meet this long felt need. Further the formulation of Appendix D is not represented in the broadest claim. The broadest claim contains no concentrations and merely states functional language that would be inherent to any semi-solid formulation comprising those two ingredients. For these reasons the Declaration is insufficient to overcome the rejections.

Response to Arguments

Applicant's arguments with respect to claims 8-13 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Agar has been used in pudding and gel food preparations for years as can be seen in the ***Food for Peace Pudding Recipes*** website

<http://www.geocities.com/Tokyo/Courtyard/8761/f07e.htm>.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICAH-PAUL YOUNG whose telephone number is (571)272-

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0608. The examiner can normally be reached on Monday-Friday 7:00-4:30; every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

/MICAHA-PAUL YOUNG/
Examiner, Art Unit 1618